IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA,	:	**CIVIL ACTION NO.**
Plaintiff,	:	
v.	:	
	:	**JURY DEMAND**
GENENTECH, INC.,	:	
Defendant.	:	

COMPLAINT

Plaintiff Trustees of the University of Pennsylvania (the "University"), by and through the undersigned attorneys, brings this suit against defendant Genentech, Inc. ("Genentech") and alleges as follows:

PARTIES

1. The University is a nonprofit corporation organized and existing under the laws of the Commonwealth of Pennsylvania, having its principal place of business in Philadelphia, Pennsylvania.

2. Genentech is a corporation organized and existing under the laws of the state of Delaware with its principal place of business at 1 DNA Way, South San Francisco, California 94080.

JURISDICTION AND VENUE

3. This Court has subject matter jurisdiction over this action under 28 U.S.C. § 1332, because the amount in controversy exceeds $75,000.00 exclusive of interest and costs, and because there is complete diversity of citizenship between the University and Genentech.

4. Venue is proper in this district under 28 U.S.C. § 1391(c), because defendant is incorporated in the state of Delaware and because, pursuant to Section 13.9 of the January 9, 2004 License Agreement between the University and Genentech ("2004 License Agreement"), the parties "submit to the exclusive jurisdiction of, and venue in, the state and Federal courts located in the State of Delaware with respect to all disputes arising under this Agreement." The 2004 License Agreement is attached hereto as Exhibit A.

5. The parties have agreed that the 2004 License Agreement "shall be governed in accordance with the laws of the Commonwealth of Pennsylvania, without giving effect to the conflict of law provisions of any jurisdiction." Exhibit A, at Section 13.8.

STATEMENT OF FACTS

6. The University owns all rights, title and interest in and to United States Patent No. 5,824,311, entitled "Treatment of tumors with monoclonal antibodies against oncogene antigens" (the "'311 Patent"). The '311 Patent is attached hereto as Exhibit B.

7. The '311 Patent discloses and claims certain novel dual-antibody cancer therapies targeting the Her2/*neu* molecule, developed by Drs. Mark Greene and Jeffrey Drebin of the University of Pennsylvania Health System.

8. Pursuant to the 2004 License Agreement, the University granted to Genentech an exclusive worldwide license under the '311 Patent to research, develop, make, have made, use, import and export, sell, have sold and offer for sale certain Licensed Products, including the administration of two antibodies in combination to treat cancer ("Combination Therapy"). The two antibodies may be administered in combination from separate vials (a "Dual-Vial Product") or from the same vial (a "Mixed Product"). *See generally* Exhibit A, at Section 1.

9. The 2004 License Agreement required that Genentech pay to the University milestone payments conditioned on certain events in the approval process for the Combination Therapy at issue. In partial consideration of the granted license, Genentech agreed to pay the University, *inter alia*: (1) a one-time milestone payment of $750,000 upon "[e]nrollment of the first patient in a controlled phase II study to evaluate the efficacy and safety of Licensed Products used in Combination therapy" ("Milestone 1"); (2) a one-time milestone payment of $3,000,000 upon "[i]nitiation of the first phase III clinical trial of a Combination Therapy" ("Milestone 2"); and (3) a one-time milestone payment of $7,000,000 upon "[t]he first to occur of: (i) the first publication of data by the Company or a third party of final results from a Phase III clinical trial sponsored by the Company, which trial demonstrates statistically significant efficacy of a Licensed Product composed of two Approved Antibodies in Combination Therapy, which publication is made in a peer reviewed journal . . . ; or (ii) the first regulatory approval of New Drug Application, Biologics License Application, or marketing approval in the United States, as appropriate, for the administration of two Approved Antibodies in Combination Therapy" ("Milestone 3"). Exhibit A, at Section 3.3.

10. The 2004 License Agreement also required that Genentech pay to the University certain earned royalties and quarterly minimum royalties. *See id.*, at Section 3.4.

11. Section 3.5 of the 2004 License Agreement required Genentech to pay to University earned royalties based on U.S. "Net Sales" of Licensed Products. Payments were to be made for each three-month period beginning on January 1, April 1, July 1, and October 1, respectively.

12. The 2004 License Agreement set forth tiered royalty rates separately for Mixed Products and Dual-Vial Products. In particular, Section 3.5 contained a chart that

provided that royalty rates would be up-tiered based on "Annual Net Sales," as follows:

ANNUAL NET SALES	MIXED PRODUCT RATES	DUAL-VIAL RATES	
		HERCEPTIN	NON-HERCEPTIN ANTIBODIES
Up to $500 Million	1.0%	0.5%	1.0%
From $500 Million up to $1.0 Billion	2.0%	1.0%	2.0%
Greater than $1.0 Billion	3.0%	1.5%	3.0%

13. In 2007, Genentech initiated a first phase III clinical trial involving the combined administration of Herceptin and a monoclonal antibody named Pertuzumab, and a dispute arose between the University and Genentech regarding whether Genentech was required to pay Milestone 2 in the amount of $3,000,000.

14. The University accused Genentech of materially breaching the 2004 License Agreement, *inter alia*, by failing to pay Milestone 2 pursuant to Section 3.3, and by failing to promptly conduct trials involving the use of Herceptin and Pertuzumab in combination, in violation of Section 2.2.

15. On November 24, 2010, after months of negotiations, the Parties entered into a settlement agreement (the "Settlement Agreement") to resolve the dispute in lieu of litigation. Pursuant to the Settlement Agreement, the parties entered into an amendment of the 2004 License Agreement (the "2010 Amendment"). The Settlement Agreement (without exhibits) and the 2010 Amendment are attached hereto as Exhibits C and D, respectively.

16. Pursuant to Section 15 of the 2010 Amendment, Section 3.5 of the 2004 License Agreement was amended so that earned royalties would be computed as follows:

"(a) When the Herceptin and Non-Herceptin Antibody elements of a Licensed Product are Sold together at a single invoice price by Genentech, its Affiliates, or

sublicensees, this shall be referred to as 'Mixed Product.' The royalty rate for Mixed Products shall be:

Combined Net Sales	Mixed Product
Up to $500 million	1.0%
From $500 million to $1.0 billion	2.0%
Greater than $1 billion	3.0%

'Combined Net Sales' in the case of a Mixed Product shall mean the Net Sales of the Mixed Product.

(b) When the Herceptin and Non-Herceptin Antibody elements of a Licensed Product are Sold at separate invoice prices by Genentech, its Affiliates, or sublicenses, this shall be referred to as a 'Dual Vial Product.' The royalty rate for Dual Vial Products that are used for Combination Therapy shall be:

Combined Net Sales	Herceptin	Non-Herceptin Antibody
Up to $500 million	0.5%	1.0%
From $500 million to $1.0 billion	1.0%	2.0%
Greater than $1 billion	1.5%	3.0%

'Combined Net Sales' in the case of a Dual Vial Product shall mean the combined Net Sales of Herceptin component and the Non-Herceptin Antibody component. The Net Sales of the Herceptin and Non-Herceptin Antibody elements of a Dual Vial Product shall be calculated according to the method in Section 3.5(c)."

17. Pursuant to Section 13 of the 2010 Amendment, as part of the settlement, the University and Genentech agreed that Genentech was required to pay Milestone 2 within 10 days of the Effective Date of the Settlement Agreement, and agreed to reduce the amount of Milestone 3 from $7,000,000 to $6,000,000.

18. Pursuant to Section 15 of the 2010 Amendment, the University and Genentech agreed that royalty rate tiers would be based on "Combined Net Sales," rather than "Annual Net Sales," such that the tiered royalty rates would be determined based on cumulative net sales during the license term rather than annual net sales.

19. The 2010 Amendment includes an integration clause asserting that all representations, understandings, or agreements are merged into and superseded by the terms of the 2010 Amendment, but explicitly does not supersede the 2004 License Agreement. *See* Exhibit D, at Section 16. The 2004 License Agreement, as amended by the 2010 Amendment, is referred to herein as the "Amended License Agreement."

20. In or about June 2012, the FDA approved Perjeta (chemical name Pertuzumab), in combination with Herceptin, to treat Her2-positive metastatic breast cancer and, beginning with the period ending June 30, 2012, Genentech began reporting sales, and computing and paying earned royalties.

21. In or about early 2015, the University began to suspect that Genentech was not calculating tiered royalty rates based on cumulative sales, or even annual sales. Instead, it appears that Genentech has been erroneously calculating tiered royalty rates based on quarterly net sales, which has no basis in either the 2004 License Agreement or the Amended License Agreement.

22. Accordingly, by a letter dated May 28, 2015, the University exercised its audit rights under Section 4.4 of the Amended License Agreement to determine the amount of Genentech's underpayment of royalties. The royalty audit commenced in or about August 2015 and is ongoing.

COUNT I

Breach of Contract

23. The University incorporates by reference the foregoing allegations as if fully restated herein.

24. The University and Genentech entered into the 2004 License Agreement whereby Genentech agreed to pay to the University earned royalty payments based on Net Sales according to royalty rates tiered based on Annual Net Sales.

25. During the negotiation of the 2010 Amendment, the parties did not negotiate or even discuss amending the royalty base from annual net sales to quarterly net sales.

26. Under the Amended License Agreement, Genentech is required to pay earned royalties according to royalty rates tiered based on cumulative net sales during the term of the license.

27. Genentech has materially breached the Amended Agreement, *inter alia*, by paying earned royalties to University based royalty rates determined based on quarterly net sales.

28. As a direct and proximate result of Genentech's breach, the University has been substantially damaged and is entitled to an amount in excess of $75,000.00, plus interest as allowed by law.

PRAYER FOR RELIEF

WHEREFORE, the University respectfully requests that this Honorable Court grant the following relief in its favor against Genentech as follows:

a) An award of compensatory damages exceeding $75,000.00, with interest at the maximum amount permitted by law; and

b) A declaration that, pursuant to the Amended License Agreement, the royalty rates for any future earned royalties will be based on tiered royalty rates determined based on cumulative net sales during the license term.

c) An award of attorneys' fees, costs, and other expenses as permitted by law; and

d) Such other and further relief as the Court may deem just and proper.

Dated: July 15, 2016

Respectfully submitted,

/s/ Colm F. Connolly

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**pro hac vice* motion to follow